



OCT - 6 2006

Janice M. Klunder
Intellectual Property Department
Millennium Pharmaceuticals, Inc.
75 Sidney Street
Cambridge MA 02139

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,780,454

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,780,454, which claims the human drug product VELCADE® (bortezomib) and pharmaceutical compositions comprising VELCADE® (bortezomib), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 918 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 918 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of March 19, 2004 (69 Fed. Reg. 13055). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} \text{ (Testing Phase) + Approval Phase} \\ &= \frac{1}{2} (1,610) + 113 \\ &= 918 \text{ days (2.5 years)}\end{aligned}$$

Since the regulatory review period began August 26, 1998, after the patent issued (July 14, 1998), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,780,454
Granted:	July 14, 1998
Original Expiration Date ¹ :	October 28, 2014
Applicant:	Julian Adams, et al.
Owner of Record:	Millennium Pharmaceuticals, Inc..


¹Subject to the provisions of 35 U.S.C. § 41(b).

Title: Boronic Ester and Acid Compositions
Product Trade Name: VELCADE® (bortezomib)
Term Extended: 918 days (2.5 years)
Expiration Date of Extension: May 3, 2017

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Patent Ext. Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.
By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to xxx at (571) 272-7755.


Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Office of Regulatory Policy
HFD - 7
5600 Fishers Lane (Rockwall II Rm. 1101)
Rockville, MD 20857

Attention: Beverly Friedman

RE: VELCADE® (bortezomib)
FDA Docket No.: 03E-0458